

Remarks

Claims 1-6 are currently pending and stand rejected. Claim 1 has been amended.

Double Patenting Rejections

The Examiner has entered a rejection under the grounds of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,319,924, which claims a method for the treatment or inhibition of cutaneous scar tissue U.S. Patent No. 6,319,924. In response to this rejection, a Terminal Disclaimer is submitted herewith, which should overcome the double patenting rejection.

The Examiner has entered a rejection on the grounds of a rejection under the grounds of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,500,857 which claims a method for stimulating subcutaneous muscles and increasing subcutaneous muscle tone. In response to this rejection, a Terminal Disclaimer is submitted herewith, which should overcome the double patenting rejection.

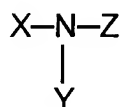
Rejections under 35 U.S.C. §102/103

In the Office Action dated March 25, 2005, the Examiner rejected claims 1-6 under 35 U.S.C. §102(e), as being anticipated by, or alternatively obvious over each of U.S. Patent No. 6,444,195 to Cole ("the '195 patent"), U.S. Patent No. 6,482,446 to Watson ("the '446 patent") or U.S. Patent No. 6,372,791 to Shapiro ("the '791 patent"), alone.

Applicant respectfully disagrees that the neither of these references, alone or in combination, discloses or suggests all elements of at least Applicant's independent claim 1. Specifically, all claims of Applicant's present invention are directed to a topical

acne composition requiring the **specific combination of:**

a) from about 0.1% to about 10% by weight of an alkanolamine of the formula:



wherein X, Y and Z are selected from the group consisting of hydrogen, C₁-C₃ alkyl groups, C₂-C₄ alkanol group, wherein at least one of X, Y, or Z is a C₂-C₄ alkanol group bearing at least one hydroxyl group and optionally at least one carboxyl group;

b) from about 0.01% to about 6% by weight tyrosine; and

c) from about 0.01% to about 10% by weight of a sulfur-containing ingredient selected from the group consisting of lipoic acid, glutathione, and mixtures thereof. (See Applicant's claim 1.)

The '195 Patent

The Examiner has cited the '195 patent (in rejecting Applicant's respective claims) for teaching acne-treating agents comprising alkanoalimine, lipoic acid, and tyrosine, (Applicant claim 1 elements) as well as and hydroxyl acids, and ascorbic acid derivatives (claims 4-5) and that said aforementioned agents are present in amounts of .001-20%.

The '195 patent is directed to sunscreens containing dibenzoylmethane derivative, one of the most commonly used UV-A absorbers (to block UV-A radiation from reaching the skin, preventing sunburn, wrinkles, skin cancer and other sun damage to skin). (See col. 1, lines 10-15, 20-23) However, as discussed in the patent, dibenzoylmethane derivatives have the problem of photochemical instability, detracting from their effectiveness and requiring reapplication of sunscreens to skin. (See col. 1,

lines 21-24.) In a direct attempt of solving this problem of photochemical instability of dibenzoylmethane derivatives, the inventors of the '195 patent discovered that the specific combination of dibenzoylmethane derivative and di/polyester of naphthalene dicarboxylic acid surprisingly increases the photo-instability of dibenzoylmethane. (See col. 1, line 65 to col. 2, line 4)

In contrast to this specificity of three combined key active agents of Applicant's claim 1, the sunscreen formulation of the '195 patent merely includes a laundry list of potential adjunct ingredients to its primary active ingredients of dibenzoylmethane and di/polyester of naphthalene. These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. (See col. 4, line 66 to col. 5, line 45.) Adjunct ingredients listed are vitamins, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing agents, and antifungal agents, to name a few. (*Id.*) There-within, alkanolamines are mentioned at col. 5 lines 5; tyrosine, included as one potential example of the adjunct ingredient of an amino acid; tyrosine is mentioned at col. 5, line 15; and lipoic acid is mentioned at col. 5, line 14. The '195 patent generally states that any of these one or more adjunct ingredients (in total) amount to 0.1-20% by weight of the final composition. (See col. 3, line 35.)

While the required ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three key ingredients, and the beneficial, surprising effects of that combination as achieved by Applicant's present invention. (*Id.*, While one of several therapeutic effects mentioned is "treat wrinkles acne, or to lighten the skin," at col. 5, line 3, there is no indication or teaching which of the several ingredients, alone or in combination, achieve that.) A general disclosure of percentage by weight of one or more of ingredients on a laundry list does

not amount to a disclosure or a suggestion of the *precise ranges of each of the key active ingredients* recited in Applicant's claim 1. There is no teaching in the '195 patent of which few, within the laundry list of the several, ingredients to combine and which to not include (nevermind in what percentages by weight of each) to arrive at Applicant's invention, nor is there motivation to look to teachings regarding *adjunct* ingredients in a sunscreen whose primary active ingredient serves as a chemical block UV-A radiation to prevent it from reaching the skin (and preventing deleterious effects – wrinkles, burn, cancer – from ever occurring), rather than *acting directly upon* the skin, to find ingredients to be employed in a specific combination to act upon the skin. Further, there is no motivation to look to the teachings of adjunct ingredients in a composition whose main ingredient does *not* act upon the cells of the skin, in order to find a specific combination of adjunct ingredients, each in specific weight percentage ranges, that must act directly upon the cells skin in topical *acne* composition for treating such an existing skin disease of *acne*, and preventing further *acne* from forming. Hence, for at least these reasons, the '195 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

The '446 Patent

The '446 patent is directed to astringent composition having viscosity values of at least 5,000 centipose, containing astringent plus alcohol, and method of use, designed to overcome the problems of consistency and resulting difficulty in use and application of astringents typically having low viscosity values. (See col. 2, lines 14-30.) To overcome these problems, the astringents of the '446 patent employ a relatively low alcohol concentration and increased viscosity values. (See col. 1, lines 32-34.) The astringents of '446 patent may further include adjunct ingredients that do not serve to address the problems the invention seeks to relieve. (See col. 2, line 61 to col. 3, line 67/) These adjunct ingredients are included merely for good measure as generally-accepted addi-

tives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sun-screen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin smoothing and soothing agents, and antifungal agents, to name a few. (*Id.*) Within the laundry list of adjunct ingredients, 2-dimethylaminoethanol is mentioned at col. 3 lines 4; tyrosine, included as one potential example of the adjunct ingredient of an amino acid; tyrosine is mentioned at col. 3, line 5 (confirm); and lipoic acid is mentioned at col. 3, line 5. The '446 patent generally states that any of these one or more adjunct ingredients (in total) amount to 0.1-20% by weight of the final composition. (See col. 3, line 11.)

While these ingredients of Applicant's claim 1 can be found buried amidst a large amount and variety of other ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients and the beneficial, surprising affects of that combination as achieved by Applicant's present invention. (*Id.*, While one of several therapeutic effects of adjunct ingredients mentioned is to "treat wrinkles and/or acne, at col. 2, line 63, there is no indication or teaching which of the several ingredients, alone or in combination, achieve that.) A general disclosure of percentage by weight of one or more of ingredients on a long list does not amount to a disclosure or a suggestion of the *precise ranges of each of the three key active ingredients* recited in Applicant's claim 1. There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include, to arrive at Applicant's invention, (nevermind in what exact percentages by weight of each) nor is there motivation to look to teachings regarding *adjunct* ingredients in an astringent whose primary active ingredients serve to bind and tighten soft tissue and tone skin to find ingredients to be employed in a specific combination to act upon the skin in a method of treating an existing skin disease, *acne*, and preventing further *acne* from forming.

Moreover, even if *arguendo*, there was a teaching of any of Applicant's ingredients, there would be motivation to combine teachings of an astringent and other alcohol-

containing compositions as they are often too drying and harsh to be used on acne-affected skin and would not be referenced for insight in treatment of the skin disease of acne. (See Application at ¶ [0032], discussing alkanolamine compositions as advantageous in light of anti-inflammatory and anti-acne properties as conventional acne products, such as astringents cause redness and inflammation to sensitive skin). Hence, for at least these reasons, the '446 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

The '791 Patent

The '791 Patent is directed to a method of promoting metabolism, energy production and uptake and utilization of oxygen in the skin, by applying a combination of i) carnitine, or salt or ester thereof, and ii) pyruvic acids or salt or ester thereof. (See Abstract) Resultantly, skin firmness, elasticity, tone, texture and barrier function is improved. (See col. 1, lines 35-38.)

In contrast to this specificity of three combined key active ingredients of Applicant's claim 1, the '791 patent merely includes a laundry list of potential adjunct ingredients to its primary active ingredients of carnitine and pyruvic acid. (See col. 4, lines 13-44.) These adjunct ingredients are included merely for good measure as generally-accepted additives, and *not* to achieve any particular goal other than for what already is known by one of skill in the art based on their inherent properties. Adjunct ingredients listed are sunscreen agents, botanical extracts, antimicrobial agents, anti-inflammatory agents, skin lightening agents, and antifungal agents, to name a few. (*Id.*) Within this laundry list of adjunct ingredients, 2-dimethylaminoethanol is mentioned at col. 4, line 24; tyrosine is mentioned at col. 4, line 55; sulfur resorcinol at col. 4, line 21; and lipoic acid is mentioned at col. 4, line 20. The '791 patent generally states that any of these one or more adjunct ingredients (in total) amount to 0.1-20% by weight of the final composition. (See col. 4, lines 30-31.) While these ingredients of Applicant's claim 1 can be found

buried amidst a large amount and variety of other adjunct ingredients provided generally in a laundry list, such mention-in-passing of each of these ingredients individually does not amount to a disclosure, nor a suggestion, of the *specific combination* of those three ingredients and the beneficial, surprising affects of that combination as achieved by Applicant's present invention. (*Id.* While one of several therapeutic effects mentioned is "treat wrinkles acne, or to lighten the skin," at col. 4, lines 19-20, there is no indication or teaching which of the several ingredients, alone or in combination, achieve that.) A general disclosure of percentage by weight of one or more of ingredients on a long list does not amount to a disclosure or a suggestion of the *precise ranges of each of the key active ingredients* recited in Applicant's claim 1. There is no teaching of which few, within the laundry list of the several, ingredients to combine and which to not include (nevermind in what percentages by weight of each) to arrive at Applicant's invention. Nor is there motivation to look to teachings regarding adjunct ingredients in a composition having carnitine-pyruvic acid active ingredients to promote oxygen consumption by the skin in order to find key active ingredients to be employed in a *specific combination* of alkanolamines, tyrosine and a sulfur composition for use in topical acne composition to treat the existing skin disease of *acne*, and prevent further *acne* from forming. Hence, for at least these reasons, the '791 patent fails to teach or suggest Applicants claims, overcoming the Examiner's rejection.

With respect to the above rejections, the Examiner repeatedly states that even if the claimed composition may not be included within the examples, and *moreover*, even if the weight amounts of each are not individually taught, it would have been readily apparent to any skilled artisan how to make the composition comprising such ingredients with titrating effect dosage. (See Office Action, page 3) Applicant respectfully disagrees. One of skill in the art could not from the teachings in the cited references and/or from his or her knowledge of the art, be able to pick out from a list of ingredients that are listed merely as adjunct or additive ingredients for their inherent properties, and know that they together these specific three would be the key ingredients of an effective

topical composition for treating and preventing acne, of the present invention. Further, one of skill in the art would have no knowledge as to provide each of the three key ingredients in their specific effective amount ranges as recited in the present claims.

Beneficial Results

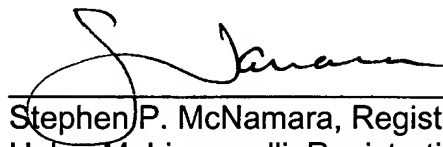
Applicant's invention achieves a novel topical acne composition for treating and preventing acne vulgaris manifested by the symptoms of pustule, papule, and comedone formation, minimizing the number and severity of lesions. The composition contains an alkanolamine of a specific formula, tyrosine, and a sulfur ingredient. A homogeneous skin complexion, and a simultaneously reduction of pore size, is achieved. The present invention results in evening out skin texture, minimizing scar formation, treating acneform scars left after resolution of the active phase, promoting clear and firm skin tone, and providing a healthier look as well as eliminating the social stigma when one suffers from acne.

The topical composition of the present invention are further advantageous in that they ameliorate skin irritation caused by conventional acne formulations so that more efficacious therapies can be devised for individual patients based on their different medical needs, including therapies that combine different treatments. The beneficial results disclosed in Applicant's invention support a finding of patentability and nonobviousness over the cited references.

Hence, for at least the aforementioned reasons, claims 1-6 are patentable and non-obvious over "the '195 patent", "the '446 patent", and "the '791 patent," whether considered alone or on combination.

Applicant respectfully asserts that the Examiner's rejection have been traversed by the aforementioned amendment and remarks. It is respectfully submitted that all of the pending claims are in order for allowance and early notice to that effect is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "S. McNamara", is written over a horizontal line.

Stephen P. McNamara, Registration No. 32,745
Helen M. Limoncelli, Registration No. 51,950
Attorneys for Applicant
ST.ONGE STEWARD JOHNSTON & REENS LLC
986 Bedford Street
Stamford, CT 06905-5619
203 324-6155